

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

UNITED STATES OF AMERICA
ex rel. LIESA KYER,
Plaintiff-Relator,

vs.

THOMAS HEALTH SYSTEM, INC., HERBERT J.
THOMAS MEMORIAL HOSPITAL
ASSOCIATION (d/b/a THOMAS MEMORIAL
HOSPITAL) CHARLESTON HOSPITAL, INC.
(d/b/a ST. FRANCIS HOSPITAL), THS
PHYSICIANS PARTNERS, INC., and BRIAN
ULERY,
Defendants.

CIVIL ACTION NO. 2:20-cv-00732

**DEFENDANT'S BRIEF ADDRESSING *LOPER BRIGHT'S*
EFFECT ON THE STARK LAW AND RELATOR'S CLAIMS**

INTRODUCTION

Physicians deserve to be paid for their services. And Congress, by enacting the Stark Law and permitting the wRVU (service-based) compensation at issue here, ensured physicians could be paid for those services while protecting patients from truly predatory referral schemes. This Court need not review page after page of federal regulations to make that determination. Rather, the best, and most logical reading of the statutorily-based and permissive compensation arrangements present in the Stark Law itself establish that Relator failed to state an articulable claim under the statute and thus the False Claims Act.

This Court appropriately posits that the Stark Law has evolved over the years to become a “labyrinth of multipart compliance requirements where the exception-to-the-exception-to-the-exception is the norm.” (Dkt. 63 p. 7 (citing Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 22-23)). And at issue here is whether Relator, after raising specific safe harbors, exceptions, and interpretations of the Stark Law, has stated a claim that Defendants’ alleged compensation arrangements run afoul of the law itself. Fortunately, despite the tangle of regulations and interpretative guidance that exists, this Court need only look to the statute to determine that no claim has been stated.

This Court requested the parties address the effect of *Loper Bright Enters. v. Raimondo* on the Stark Law and whether this Court is able to make certain determinations about definitions and exceptions under the law. (Dkt. 63 p. 10). To assist the Court, Defendants address *Loper Bright*’s direction to the federal courts, briefly summarize Relator’s allegations, and detail the scope of the Stark Law.

1. The Supreme Court's Direction to Federal Courts under *Loper Bright*.

Over forty years ago, the Supreme Court established what is familiarly known as *Chevron* deference. *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1981). Under *Chevron* deference, courts could consider whether an administrative agency's interpretation of a statute was enforceable by deferring to the agency's own interpretation of that statute. *Chevron*, 467 U.S. 837, 839, 844 (1981). This deference to an administrative agency was warranted if the agency in question was interpreting a statute Congress charged it with administering and the statute itself was either silent or ambiguous as to the specific issue being addressed by the agency. *Id.* at 843. When these conditions were met, courts deferred to an agency's reasonable interpretation of the law. *Id.* at 842-843.

Recently, the Supreme Court overturned this long-standing precedent. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024). The Supreme Court held that under the Administrative Procedure Act, courts must exercise independent judgment when deciding whether an agency acted within its statutory authority. *Loper Bright*, 144 S.Ct. 2244, 2273. It cannot defer to the agency's own interpretation of the statute, as previously allowed under *Chevron*. *Id.* at 2273.

The Supreme Court clarified this new burden on federal courts: "Statutes, no matter how impenetrable, do—in fact, must—have a single, best meaning. That is the whole point of having written statutes." *Loper Bright*, 144 S.Ct. 2244, 2266. The best reading aligns with a statute's meaning "at the time of enactment" and is "the reading the court would have reached if no agency were involved." *Id.* Anything short of the best reading "is not permissible." *Id.* To arrive at that determination, courts must use the familiar tools of statutory interpretation, construing the law "with clear heads and honest hearts, not with an eye to policy preferences that have not made it into the statute." *Id.* at 2268 (cleaned up).

When, as here, “Congress has directly spoken to the precise question at issue... [it] is the end of the matter.” *Washington Hosp. Ctr. v. Bowen*, 795 F.2d 139, 143 (D.C. Cir. 1986). Courts “need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous.” *Loper Bright Enters.*, 144 S. Ct. at 2273.

2. Relator Acknowledges the Stark Law’s Express Statutory Exceptions.

To better articulate the Stark Law’s best meaning, it is critical to understand the context in which Defendants are alleged to have violated the statute. Simply stated, the Stark Law prohibits physicians from making referrals to entities with which they have financial relationships. 42 U.S.C. 1395nn(a)(1) (*see also* Dkt. 52 ¶21). But as this Court notes, there is much more nuance to such a determination. (Dkt. 63 pp. 6, 9-10).

At its core, the *First Amended Complaint* goes far beyond simply alleging Defendants had financial relationships with entities to which patients were referred. Relator invokes the statute’s various exceptions and broadly alleges Defendants violated the Stark Law by way of the service-based compensation methodologies put in place by the hospitals where these physicians performed their services. (Dkt. 52 ¶¶98-122). Relator goes further, arguing that wRVU compensation violates the Stark Law because physician compensation “took into account the volume or value of referrals to the Thomas Health Hospitals from the physicians.” (Dkt. 52 ¶ 130). Relator thereafter makes the conclusory statement: “[D]efendants took into [] account the value of referrals. . . and [this] was not fair market value or commercially reasonable for services actually provided. . .” (Dkt. 52 ¶130-131). Relator pulls these key terms—volume and value of referrals and fair market value (as well as others scattered throughout the *First Amended Complaint*)—from the Stark Law’s various exceptions and safe harbors, including, among others:

- The Physician Services exception - 42 U.S.C. 1395nn(b)(1) and 1395nn(e)(3);
- In-Office Ancillary Services exception - 42 U.S.C. 1395nn(b)(2); and

- Bona Fide Employment Relationships exception – 42 U.S.C. 1395nn(e)(2).

These exceptions are replete with other key terms, qualifiers, and clarifications that have been interpreted by CMS and its voluminous regulations over time. And, as Defendants argue in their *Joint Motion to Dismiss*, tracking which specific violations and exceptions Relator relies on and attempts to overcome in her pleadings is an almost impossible task given the lack of specificity in the *First Amended Complaint*. (See generally Dkt. 52). Yet Defendants and this Court have determined that, at least facially, Relator relies on the existence of a compensation arrangement between Defendants that includes compensation that is “above fair market value.” (Dkt. 52 ¶245). But to qualify these exceptions, Relator must first properly allege the existence of a compensation arrangement prohibited by the Stark Law.

Even so, it is unclear in the *First Amended Complaint* whether Relator argues that Defendants maintain a direct or indirect compensation arrangement—terms that play critically into the exceptions raised by Relator if relying on CMS’ regulatory interpretations. In paragraph 95, Relator argues that “remuneration passes between the physicians and the Thomas Health Hospitals in the form, *inter alia*, of bonuses and other compensation and exclusive referrals, thus creating a direct compensation relationship.” (Dkt. 52 ¶95). In the very next paragraph, Relator argues: “*In addition*, the physician compensation arrangements . . . *also form* the basis for an indirect financial relationship with Thomas Health . . .” (Dkt. 52 ¶96) (emphasis added). Yet elsewhere in the *First Amended Complaint*, Relator alleges that these compensation arrangements are independent of each other and argues for each in the alternative. (Dkt. 52 p. 30). Setting aside the fact that both of these allegations cannot be true at the same time—meaning the relationship is either direct or indirect—Relator spends the rest of the *First Amended Complaint* explaining the circumstances that she believes are violative of the Stark Law.

Relator summarizes her allegations and illuminates which part of the Stark Law she relies on in alleging that Defendants violated the statute:

In compensating the physicians, THSPP, subsidized by Thomas Health and Thomas Health Hospitals, pays remuneration that: varies with, and takes into account the volume and value of referrals; is based on services not actually provided by the physicians; does not serve a legitimate business purpose; and, exceeds what would be considered fair market value or commercially reasonable. (citation omitted).

Accordingly, the arrangements do not comply with an exception under the Stark Law, and Thomas Health and its Thomas Health Hospitals are prohibited from submitting claims for designated health services to federally financed healthcare programs pursuant to referrals from such physicians.

(Dkt. 52 ¶¶96-97). To explain these allegations, Relator examines the wRVU compensation arrangements between Defendants. (Dkt. 52 ¶¶167-210). Relator also alleges that services were performed by other mid-level providers and thus not payable. (Dkt. 52 ¶156).

This Court—following the maze of exceptions and qualifications to the Stark Law’s prohibitions—conveyed it cannot determine whether Relator properly stated a claim upon which relief can be granted without first understanding if these exceptions raised by the Relator are appropriate under Stark. (Dkt. 63 p. 9-10). Fortunately, the cumbersome statute provides Defendants the protections and permissions that defeat Relator’s claim.

3. The Stark Law Expressly Permits the Compensation Arrangements Alleged by Relator.

The Stark Law, on its face, allows the service-based compensation arrangements specifically alleged by Relator in her *First Amended Complaint*. (See generally Dkt. 52).

It is undisputed that the Stark Law prohibits physicians from making referrals to entities with which they have financial relationships. 42 U.S.C. 1395nn(a)(1). The Stark Law defines a “financial relationship” to include “a compensation arrangement” in which “remuneration” is paid

by a hospital to a referring physician “directly or indirectly, overtly or covertly, in cash or in kind.” 42 U.S.C. §§ 1395nn(a)(2), (h)(1).

Relator relies on an obfuscated interpretation of this definition’s regulatory offspring in an attempt to define a Stark Law violation. But this Court does not need to rely on or explore the regulatory landslide that has developed over the years to simply find that Relator has failed to state a claim. Instead, this Court need only look to the statute. As the Supreme Court stated in *Loper Bright*, the best reading aligns with a statute’s meaning “at the time of enactment” and is “‘the reading the court would have reached’ if no agency were involved.” *Loper Bright*, 144 S.Ct. 2244, 2266. To arrive at that determination, courts must use the familiar tools of statutory interpretation, construing the law “with clear heads and honest hearts, not with an eye to policy preferences that have not made it into the statute.” *Id.* at 2268 (cleaned up).

But here the Court cannot look to the statute to untangle Relator’s allegations because the definition of “indirect compensation arrangement” was prescribed by CMS in 66 Fed. Reg. 856 (Stark Phase I Final Rule) based on the Agency’s interpretation of “what constitutes a financial relationship.” 66 Fed. Reg. 856, at 863 (Jan. 4, 2001). Even more, the terms “financial relationship,” “compensation arrangement,” “referral,” and “remuneration” are *not* concepts or definitions where Congress specifically invited the Secretary, via statute, to establish additional terms and conditions or take action in any way.

Nor did Congress specifically authorize or request that the Secretary create guidance regarding “indirect compensation arrangements” or “indirect financial relationships.” It was not until the Stark Phase I regulations were issued that the terminology of “direct compensation arrangement” or “direct financial relationship” also became relevant to the Stark Law landscape. 66 Fed. Reg. 856, at 864 (Jan. 4, 2001). But a logical reading of the statute itself avoids any

necessity for these regulatory interpretations. If the simple existence of a compensation arrangement created a violation of the Stark Law, then nearly every hospital/physician relationship in the country would violate the law. The statutory definition of compensation arrangement confirms this:

(1) Compensation arrangement; remuneration

- (A)** The term “compensation arrangement” means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).
- (B)** The term “remuneration” includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.

42 U.S.C.A. § 1395nn(h)(1)(A)-(B).¹ The broad definition of “compensation arrangement,” when separated from the statute’s other exceptions and qualifiers, seems to prohibit any referral submitted under any compensation arrangement. But such a simplistic reading of the statute—one that prohibits any compensation arrangement—would lead to absurd results where physicians could never refer a patient to a hospital or healthcare system with which the physician was related. Physicians would thus be required to send patients hours away to other systems or require patients to see less qualified providers simply because a physician entered into a bona fide employment relationship (or some other permissive relationship) with the area’s top-tier providers. To avoid this absurd result, this Court must read the blanket prohibition in conjunction with the clear exceptions and permissions present in the statute.

When it enacted the Stark Law, Congress authorized the Secretary of the Department of Health and Human Services to take action in several ways, including:

- 1) In every statutory exception applicable to compensation arrangements, Congress granted the Secretary authority to impose “such other requirements...by regulation as needed to protect against program or patient abuse.” 42 U.S.C. § 1395nn(e)(2)(D);

¹ The carve out in subparagraph (C) is a narrow invitation for the Secretary to impose regulation related to payments made by insurers or self-insured plans to physicians.

- 2) To create additional standards for regarding the definition of “group practice.” 42 U.S.C. § 1395nn(h)(4)(A);
- 3) To establish any additional terms and conditions regarding the In-Office Ancillary Services Exception. 42 U.S.C. § 1395nn(b)(2)(A)-(B); and
- 4) To determine any other financial relationship applicable to the Stark Law exceptions for both Ownership and Compensation that the Secretary deems do not pose a risk of program or patient abuse. 42 U.S.C. § 1395nn(b)(4).

This statutory authority explicitly authorizes the Secretary of HHS to enforce the exceptions specifically outlined in the statute itself, as well as the ability to “determine any other financial relationship applicable to the Stark Law exceptions.” 42 U.S.C. § 1395nn(b)(4). And while many Stark Law exceptions are regulatory, there are several that are also found in the statute enacted by Congress. The exception for bona fide employment relationships, which is expressly relied upon by Relator in this case, is statutory. It states:

(2) Bona fide employment relationships

Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if—

(A) the employment is for identifiable services,

(B) the amount of the remuneration under the employment—

(i) is consistent with the fair market value of the services, and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,

(C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and

(D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).

42 U.S.C. § 1395nn(e)(2). Exceptions under the Stark Law for bona fide employment relationships have been fundamental to the Congressional intent of this statute going all the way back to its infancy. When looking back through the legislative history of the Stark Law, the proposed House Bill for the *Prohibition of Certain Financial Arrangements Between Referring Physicians and Providers of Medicare Covered Items and Services*, which would eventually evolve into the modern-day Stark Law statute, included an exception for employment services and also contemplated that the Secretary “may impose [other requirements] by regulation as needed to protect against program or patient abuse.” H.R. Conf. Rep. 101-386 at 845, 848-849, 853.

This exception, as well as Congress’ express authorization of the Secretary to create supporting regulations, buttress the arguments raised in *Defendants’ Joint Motion to Dismiss* and allow for the wRVU compensation methods alleged. They similarly dispel the use of market benchmarks theorized in Relator’s desperate search for a technical misstep by Defendants.

Most critically, the bona fide employment exception, codified in statute and expounded upon by the Secretary as permitted by the Stark Law, has been deemed to permit wRVU compensation in the format described in the *First Amended Complaint*. (Dkt. 63 p. 9-10). Congress and CMS specifically considered this payment method to allow physicians to be paid for the services they perform under any compensation arrangement. CMS even clarified that a unit-based compensation formula (in both a direct or indirect compensation model) does not take into account the volume and value of referrals. On its face, this exception permits the service-based

compensation alleged in the *First Amended Complaint* and thus there can be no Stark Law violation. Even more, as the Stark Law allows the Secretary to “determine any other financial relationship applicable to the Stark Law exceptions,” CMS has stated that arbitrary benchmarks—for the purposes of determining fair market value—are inappropriate. 85 Fed. Reg. 77558.

Ultimately, Relator has attempted to create a Stark Law violation by cherry-picking terms and concepts from various regulations and by theorizing concepts not spelled out in the statutory or regulatory language. But this Court does not have to trace those arguments or attempt to find supporting law for Relator’s non-specific claims of fraud. Instead, this Court need only look to the Stark Law itself.

CONCLUSION

The Stark Law protects patients by prohibiting referrals, but allows physicians to still be paid for the services they perform under either a direct or indirect compensation arrangement. The single, best meaning of the Stark Law is one that specifically allows for the bona fide employment exception, the physician services exception, and the in-office ancillary services exceptions—exceptions that do not prohibit wRVU compensation, allow for incident-to billing, and do not require arbitrary market benchmarks to define fair market value. This Court can determine—from the Stark Law itself—that Relator has not stated a claim upon which relief may be granted.

**THOMAS HEALTH SYSTEM, INC.,
HERBERT J. THOMAS MEMORIAL
HOSPITAL ASSOCIATION d/b/a THOMAS
MEMORIAL HOSPITAL, CHARLESTON
HOSPITAL, INC. d/b/a ST. FRANCIS
HOSPITAL, THS PHYSICIANS PARTNERS,
INC., and BRIAN ULERY**

By: */s/ Robert L. Massie*

Of Counsel

Robert L. Massie
NELSON MULLINS RILEY &
SCARBOROUGH LLP
949 Third Avenue, Suite 200
Huntington, WV 25701
Ph: 304-526-3502
Email: bob.massie@nelsonmullins.com

And

David B. Honig, Pro Hac Vice
Matthew M. Schappa, Pro Hac Vice
HALL RENDER KILLIAN HEATH &
LYMAN, P.C.
500 N. Meridian Street, Ste. 400
Indianapolis, IN 46204
Ph: 317-633-4884
Email: dhonig@hallrender.com
Email: mschappa@hallrender.com

Counsel for Defendants

CERTIFICATE OF SERVICE

I, Robert L. Massie, hereby certify that a true and correct copy of the foregoing ***“Defendant’s Brief Addressing Loper Bright’s Effect on the Stark Law and Relator’s Claims”*** has been served electronically by the Court’s CM/ECF system which will automatically send notice of such filing to counsel of record this 4th day of October, 2024.

/s/ Robert L. Massie
Robert L. Massie (WV Bar #5743)